Message

From: Stratton Edwards [sedwards@capitolhillcg.com]
Sent: 6/1/2018 6:43:07 PM
To: Beck, Nancy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=168ecb5184ac44de95a913297f353745-Beck, Nancy]
CC: Mike Ruley [mruley@alliedbioscience.com]
Subject: Follow up to Allied BioScience meeting
Attachments: ATT00001.txt

Good Afternoon Nancy,

Thank you again for taking the time to meet with Mike Ruley, CEO of Allied BioScience and Jack Victory from our firm in April. Jack was stepping in for me that day as I had a family commitment. I am following up to that meeting to fill in holes since I was not there, and look for a some direction moving forward.

I understand there still is no clarity on where we land within the current categories that the EPA uses for different types of disinfectant claims for products that are used in hospital settings. Our coating is to be used **in conjunction with** disinfection products and practices, not replacing them. Am I correct then that the current category is not appropriate?

At the meeting, you had suggested that the best path forward would most likely be to create a new category for this unique technology versus changing the rule making process. I believe you stated that the next steps would be establishing sideboards, creating the category, and translating it into language for review. Would this be guidance, rulemaking, something else regulatory, or do you believe we need legislation?

ABS's first formulation, PRIA A540, is in review right now for Microbiostatic claims (mainly due to the limited nature of current established categories). The anticipated approval date is in October of this year. Their science team is scheduling a call with the EPA efficacy team (Kristen Willis) to review a new proposed protocol for residual activity of a polymer coating when used in conjunction with hospital disinfectants. We would anticipate using this approved residual protocol on both formulations and would submit for formal PRIA protocol review.

For the formulation with the new active ingredient (AI), we realize that even by creating a new category, ABS would not waive the requirements of registering a new AI. They are in the final stages of confirming the data requirements for the registration of this new AI and will perform testing concurrent to the protocol review. Based on the data requirements table that they are proposing, they anticipate completing the data sets and having a registration package submitted within 6-9 months.

You clearly know the impact our formulations could have in the interest of public health and we are eager to move as quickly as possible.

With that update on where we are with our submissions, what else—either on the new category development, or otherwise—do you need from us or should we be doing?

Thank you and I look forward to talking with you soon,

Stratton

Stratton Edwards
Legislative Counsel

Capitol Hill Consulting Group
Government Relations Professionals
409 S. Capitol Street, SW
Suite 608
Washington, DC 20003

Cell: Ex. 6
Office: (202) 488-0101
Web: capitolhillcg.com